REMARKS

Claims 1-4, 7-14, 16-27, 29, 30, 33, and 34 remain in the application. Claims 1, 11, 17, 19, 29, and 30 have been amended. Claims 35 and 36 have been added. Minor amendments have been made to the specification. A version with markings to show changes made follows page 13. Claims 5, 6, 15, 28, 31, and 32 have been cancelled. A corrected ABSTRACT OF THE DISCLOSURE is being submitted. Corrected drawings are being submitted. Reconsideration of this application, as amended, is respectfully requested.

Claim 1 has been amended to recite that a movable applicator introduces at least one test material directly into each of the plurality of recording stations; the movable applicator is automated; and the electrophysiological data is collected from each of the plurality of recording stations. Support for these changes can be found at page 12, lines 2-7, at page 21, lines 3-22, at page 4, lines 10-12, and at page 5, lines 11-21 of the specification, and in claim 6, as originally filed. Claim 1 has been further amended to delete the phrase "from each of said plurality of recording stations concurrently." In view of the additions made to claim 1, it was determined that this phrase is not needed to describe the method of this invention.

Claim 11 has been amended to recite that the apparatus includes a movable applicator for dispensing a test material directly into a recording stations; and the apparatus includes a control system for (1) controlling said (a) plurality of recording stations and said (b) movable applicator and (2) for collecting said electrophysiological data from said plurality of tests. Support for these changes can be found at page 12, lines 2-7, at page 21, lines 3-22, at page 5, lines 16-19, and at page 10, lines 15-16 of the specification and in claim 15, as originally filed. Claim 11 has been further amended to delete the term "concurrently." Upon reviewing claim 11, it was determined that this term is not needed to describe the apparatus of this invention.

Claims 17, 19, 29, and 30 have been amended to conform to claim 11.

Claim 35 has been added to indicate that the tests can be run in sequence. Claim 36 has been added to indicate that the tests can be run

concurrently. Support for these claims can be found at page 4, lines 12-18 of the specification.

Claims 1-34 were rejected under 35 U. S. C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been addressed by the amendments to claims 1 and 11.

Claim 1 now recites that electrophysiological data is collected from each of the plurality of tests from each of the plurality of recording stations. Claim 11 now recites that the apparatus includes a control system (1) for controlling the (a) plurality of recording stations and the (b) movable applicator and (2) for collecting the electrophysiological data from the plurality of tests.

Claims 1-3, 5-7, 11-15, 20, 21, 23, 24, 26-28, and 30 were rejected under 35 U. S. C. § 102 (b) and (e) as being anticipated by Sweeten, et al., U. S. Patent No. 3,696,805. This rejection has been addressed by the amendments to claims 1, 11, and 30.

Sweeten et al., U. S. Patent No. 3,696,805 (hereinafter "Sweeten et al."), discloses medical examining laboratories, particularly an annulus defining a plurality of private medical examining rooms surrounding an inner core and a plurality of medical instruments mounted upon a carousel rotating within said core, so as to deliver said instruments within said individual medical examining rooms.

The claims of the present application require a movable applicator that introduces at least one test material directly into a recording station in order to obtain electrophysiological data. As defined in the application at page 9, lines 20-22, the term "applicator" means a fluid-handling device that aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. As defined in the application at page 9, lines 13-15, the expression "test material" means a substance, such as, for example, a compound, that is being tested for stimulatory, inhibitory, or modulatory activity on the test subject. Sweeten et al. is concerned with delivering instruments to individual medical examining rooms. A "test material" is not a medical instrument; a "recording station" is not an examining room; an "applicator" is not a medical instrument. In view of the foregoing major

distinctions between Sweeten et al. and the components of the present invention, it is submitted that Sweeten et al. does not anticipate any of the claims of this application.

Claims 1-3, 5-12, 14-16, 20, 21, 23, 27, 28, and 30 were rejected under 35 U. S. C. § 102 (b) and (e) as being anticipated by Kirk, et al., U. S. Patent No. 5,390,238. This rejection has been addressed by the amendments to claims 1, 11, and 30.

Kirk et al., U. S. Patent No. 5,390,238 (hereinafter "Kirk et al."), discloses a home health and communications support system and method which includes at least one health support unit for monitoring and supporting a patient, at least one monitoring terminal, and a network server coupled between the at least one health support unit and the at least one monitoring terminal for exchanging information between the at least one health support unit and the at least one monitoring terminal. The health support unit comprises a medication controller, communications module for interacting with the patient, central data processor, and external communications interface. The central data processor stores and manipulates patient data generated by the medication controller and by the communications module for patient interaction. The external communications interface allows access to patient data and accepts data from an external source.

The claims of the present application require a movable applicator that introduces at least one test material directly into a recording station in order to obtain electrophysiological data. As defined in the application at page 9, lines 20-22, the term "applicator" means a fluid-handling device that aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. As defined in the application at page 9, lines 13-15, the expression "test material" means a substance, such as, for example, a compound, that is being tested for stimulatory, inhibitory, or modulatory activity on the test subject. Kirk et al. is concerned with a computer-controlled system for storing and manipulating patient data generated by a medication controller and by a communications module for patient interaction. Kirk et al. says not a thing about an "applicator" or a "test material", as these expressions are defined herein. Furthermore, Kirk et al. does not disclose or suggest that the system described therein has a movable applicator, which

component is required in the method and the apparatus of the present invention. In view of the foregoing, it is submitted that Kirk et al. does not anticipate any of the claims of this application.

Claims 1-7, 11-15, 17-21, 23, 24, and 26-34 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over Sweeten et al., U. S. Patent No. 3,696,805 in view of Anderson et al., U. S. Patent No. 3,998,215. This rejection has been addressed by the amendments to claims 1, 11, 17, 19, 29, and 30.

Anderson et al., U. S. Patent No. 3,998,215 (hereinafter "Anderson et al."), discloses a gel pad impregnated in a porous matrix or held within a cavity, an electrically conductive hydrogel capable of transferring electrical signals between the human body and an electrode of an electrical sensing device when the hydrogel is in contact with the body surface. The hydrogel is lightly adherent to the body surface but sufficiently cohesive so that no residue remains when the pad is removed therefrom.

As stated previously, the claims of the present application require a movable applicator that introduces at least one test material directly into a recording station in order to obtain electrophysiological data. As defined in the application at page 9, lines 20-22, the term "applicator" means a fluid-handling device that aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. As defined in the application at page 9, lines 13-15, the expression "test material" means a substance, such as, for example, a compound, that is being tested for stimulatory, inhibitory, or modulatory activity on the test subject. Sweeten et al. is concerned with delivering instruments to individual medical examining rooms. A "test material" is not a medical instrument; a recording station is not an examining room; an "applicator" is not a medical instrument. Anderson et al. does indeed disclose a device for attaching electrodes to the human body. However, Anderson et al. fails to disclose or suggest any information that would convert a medical instrument to a test material, an examining room to a recording station, or a medical instrument to an applicator, as the expressions "test material", "recording station", and "applicator" are used in this application. In view of the foregoing, it is submitted that the combination of

Sweeten et al. and Anderson et al. does not render any of the claims of this application obvious to one of ordinary skill in the art.

Claims 1-3, 5-16, 20-28, and 30 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over Segalowitz, U. S. Patent No. 5,511,553. This rejection has been addressed by the amendments to claims 1, 11, and 30.

Segalowitz, U. S. Patent No. 5,511,553 (hereinafter "Segalowitz"), discloses a device, system, and method for monitoring continuously and simultaneously multiple physiological parameters from a patient, comprising a precordial strip-patch having first and second surfaces and multi-layer flexible structure permitting data by radio frequency or single wire or fiberoptic to hardware recording and display monitor. A plurality of conductive contact elements and microsensors are mounted in spaced apart positions on said strip-patch device-system permitting simultaneously and continuous detection, microprocessing, and transmission of microsensored and detected physiological data for monitoring standard 12-lead ECG, cardiac output, respiration rate, peripheral blood oximetry, temperature of a patient, and electrocardiographic fetal heart monitoring, via a single wavelength or radio frequency transmission or single-wire or single fiberoptic connection in recording hardware or display monitor.

As stated previously, the claims of the present application require a movable applicator that introduces at least one test material directly into each of a plurality of recording stations in order to obtain electrophysiological data. As defined in the application at page 9, lines 20-22, the term "applicator" means a fluid-handling device that aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. As defined in the application at page 9, lines 13-15, the expression "test material" means a substance, such as, for example, a compound, that is being tested for stimulatory, inhibitory, or modulatory activity on the test subject. Segalowitz is concerned with such medical tests as ECG, cardiac output, respiration rate, peripheral blood oximetry, temperature of a patient, and electrocardiographic fetal heart monitoring. The tests described in Segalowitz do not involve the transfer of fluids; thus, Segalowitz is not concerned with an apparatus or a method that that involves handling of fluids wherein an

applicator aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. In view of the foregoing distinctions, it is submitted that Segalowitz does not render any of the claims of this application obvious to one of ordinary skill in the art.

Claims 1-34 were rejected under 35 U. S. C. § 103 (a) as being unpatentable over Segalowitz, U. S. Patent No. 5,511,553 in view of Anderson et al., U. S. Patent No. 3,998,215. This rejection has been addressed by the amendments to claims 1, 11, 17, 19, 29, and 30.

As stated previously, Segalowitz is concerned with such medical tests as ECG, cardiac output, respiration rate, peripheral blood oximetry, temperature of a patient, and electrocardiographic fetal heart monitoring. The tests described in Segalowitz do not involve the transfer of fluids; thus, Segalowitz is not concerned with an apparatus or a method that that involves handling of fluids wherein an applicator aspirates test materials (e.g., compounds of interest) from vessels and dispenses them into recording stations. Anderson et al. does indeed disclose a device for attaching electrodes to the human body. However, Anderson et al. fails to disclose or suggest any information that would convert the components described in Segalowitz to a test material, a recording station, or an applicator, as the expressions "test material", "recording station", and "applicator" are used in this application. In view of the foregoing, it is submitted that the combination of Segalowitz and Anderson et al. does not render any of the claims of this application obvious to one of ordinary skill in the art.

In view of the foregoing, it is submitted that claims 1-4, 7-14, 16-27, 29, 30, 33, and 34, as amended, and new claims 35 and 36 are in condition for allowance, and official Notice of Allowance is respectfully requested.

It is requested that the Examiner consider the references listed in the Information Disclosure Statement mailed June 20, 2000. A copy of Form PTO-1449 and a copy of the return receipt post card are attached hereto, following page 19. Please note that although the post card indicates that eight references were enclosed, this indication is erroneous in that all nine of the references listed on Form PTO-1449 were actually enclosed.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Kindly rewrite claims 1, 11, 17, 19, 29, and 30 as follows:

1. (Once amended) A method for running a plurality of tests [concurrently] to obtain electrophysiological data, said method comprising the steps of:

(a) providing a plurality of recording stations, each of said recording stations containing at least one test subject;

(b) introducing at least one test material into [each] a first one of said plurality of recording stations, wherein a movable applicator introduces said at least one test material of step (b) directly into said first one of said plurality of recording stations, wherein said movable applicator is automated;

(c) introducing at least one test material into a second one of said plurality of recording stations, wherein a movable applicator introduces said at least one test material of step (c) directly into said second one of said plurality of recording stations, wherein said movable applicator is automated; and

[(c)] (d) collecting said electrophysiological data from each of said plurality of tests [from each of said plurality of recording stations concurrently].

11. (Once amended) An apparatus [for] capable of running a plurality of tests [concurrently] to obtain electrophysiological data, said apparatus comprising:

(a) a plurality of recording stations for holding a plurality of test subjects, at least one test subject per recording station;

(b) a [means] movable applicator for dispensing [at least one] a test material directly into [each of said recording stations] a recording station; and

(c) a [means] control system (1) for controlling said (a) plurality of recording stations and said (b) movable applicator and (2) for collecting said electrophysiological data from said plurality of tests.

17. (Once amended) The apparatus of claim 11, wherein said apparatus further includes a wash station for washing said movable applicator.

19. (Once amended) The apparatus of claim 17, wherein said means for washing said movable applicator is capable of washing the inside of said movable applicator, the outside of said movable applicator, or both the inside and outside of said movable applicator.

29. (Once amended) The apparatus of claim [28] 11, wherein said movable applicator includes:

(a) a means for reducing carryover; and

(b) a means for allowing air to escape.

30. (Once amended) The apparatus of claim [28] 11, wherein said movable applicator is capable of being adjusted with respect to position.

IN THE SPECIFICATION

Please replace the paragraph beginning at page 8, line 28, with the following:

As used herein, the expression "ligand-gated ion-channel" means a transmembrane protein unit that acts as a gate for one or more charged species to move into or out of a cell. The state of the ligand-gated ion-channel is controlled primarily by the binding of small molecules (ligands) to either the protein unit itself or to a related area. Similarly, the expression "voltage-gated ion channel" refers to an ion channel that is controlled primarily by a voltage gradient, which gradient is generally similar to the range of electrical potentials observed in biological cells. The expression "voltage clamping" means a technique for measuring the flow of current through a cell

membrane by holding its voltage constant. See, for example, "Electrophysiological Recordings from *Xenopus* Oocytes", Walter Stuhmer, *Methods in Enzymology*, Vol. 293, Academic Press (1998). The expression "test subject" means the object that is to be subjected to a test material. In clinical trials, humans are the test subjects. In the present invention, representative examples of test subjects include, but are not limited to, a biological cell, such as an oocyte expressing ion channels of interest, a section of cell membrane, an ion channel in an artificial membrane, or some other material permitting electrical control and measurement of ion channel activity. The expression "test material" means a substance, e. g. a compound, that is being tested for stimulatory, inhibitory or modulatory activity on the test subject. The term "modulator" means a test material that alters the response of a test subject. The term "agonist" means a substance that stimulates a receptor. The term "antagonist" means a compound that blocks the activity of an agonist. The expression "recovery time" means a refractory period needed by the test subject after a stimulus is applied thereto so that the test subject can respond fully to the next-applied stimulus. The term "applicator" means a fluid-handling device that aspirates test materials (e. g., compounds of interest) from vessels and dispenses them into [flowcells] recording stations. The flowcell includes a "channel" or "chamber" into which fluid perfuses and allows for the transient application of test material to the test subject. Such a fluid may be, for example, a physiological saline solution that maintains viability of the test subject. The term "bath" refers to fluid surrounding and in contact with the test subject. The expression "perfusion bath" refers to fluid flowing continuously around the test subject with fresh fluid entering the bath and spent fluid exiting the bath at equal rates of flow. The expression "perfusion system" refers to the collection of devices providing a perfusion bath, such as the flowcell and its chambers or channels, tubing to instill fluid into the perfusion bath and remove fluid from the perfusion bath, and pumps or other sources of negative and positive pressure utilized to move fluid through the system. The expression "dead volume" means the volume contained within a fluid-handling component (e. g., tube or applicator)

that is not utilized during an operation. In the case of this invention, the dead volume is the volume of a test material, e. g., a compound, that is aspirated from a storage vessel but not eventually dispensed into the recording station. Alternatively, "dead volume" can refer to a volume of fluid that is not exchanged by flow of the fluid, such as, for example, water trapped in a pocket at the edge of a stream. In this invention, the alternative meaning of dead volume is the area of the fluid region of the recording station that is not washed quickly by the perfusion bath.

Please replace the paragraph beginning at page 14, line 15, with the following:

The most direct approach for introducing a test material, e. g. a chemical compound, into the recording station 16 would involve the steps of aspirating the test material from a reagent vessel 36 and introducing the aspirated test material to the channel 42 of the flowcell 40. However, in the preferred embodiment, care must be taken so that the test subject in the channel 42 is not exposed to the test material before the intended time of application. In addition, in the preferred embodiment, the applicator 32 should be in contact with the fluid in the channel 42 prior to commencing application of the test material in order to minimize mechanical disturbance of the perfusion bath. Essentially, test material at the end 32a of the applicator 32, both in the interior of the applicator 32 and on the exterior surface of the applicator 32, will spread throughout the channel 42 in the flowcell 40 once the applicator 32 touches the fluid in the channel 42 (see FIGS. 7A, 7B, and 7C, where the test material is represented by diagonal lines running from the upper right to the lower left). This spread of the test material would be undesirable, because the test subject T would be exposed to the test material prior to the intended time. However, this spread of the test [materia lcan] material can be prevented by first creating a safety gap 62 at the end 32a of the applicator 32 and then washing the interior of the applicator 32 and the

exterior surface of the applicator 32 prior to application of the test material (see FIGS. 7D, 7E, 7F, 7G, and 7H, where the test material is represented by diagonal lines running from the upper right to the lower left). During this washing procedure, the applicator 32 is positioned and held in the wash station 22 for an interval of time sufficient to complete the intended wash operation. During the application operation, the applicator 32 is positioned and held in the channel 42 of the flowcell 40 for an arbitrary interval of time prior to initiating the flow of test material. In this manner, accurate baseline data can be acquired before the test material is introduced into the channel 42 of the flowcell 40 and subsequently to the test subject T.